

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

JANE DOE,	:	
	:	CASE NO.
Plaintiff,	:	
v.	:	JUDGE
	:	
UNITEDHEALTHCARE LIFE INSURANCE CO.,	:	MAGISTRATE JUDGE
9200 Worthington Rd.	:	
Westerville, Ohio 43082	:	
Defendant.	:	

COMPLAINT

I. Preliminary Statement

1. This action seeks declaratory, injunctive, and equitable relief, benefits, prejudgment and postjudgment interest, costs, and attorneys' fees for the unreasonable denial of benefits in violation of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1101 *et seq.*, when Defendant UnitedHealthcare Life Insurance Company (UHC) refused to reimburse Plaintiff Jane Doe (Ms. Doe) for a medically necessary prescription, giving as its specific reason that the drug, Ozempic, was limited to individuals with type-2 diabetes and experimental, investigational, or unproven for other use, even though in fact the United States Food and Drug Administration (FDA) changed that limit in 2021, and UHC never otherwise explained its rejection of Ms. Doe's treating physician's decision to prescribe Ozempic, an expensive drug, or reconciled its earlier recurrent reimbursement of an inexpensive drug, Metformin, that was, like Ozempic, primarily for the treatment of individuals with type-2 diabetes, and had been prescribed and taken by Ms. Doe who has been diagnosed as pre-diabetic and insulin resistant.

II. Jurisdiction and Venue

2. This action arises under ERISA, 29 U.S.C. §§ 1132(a); 1133 because Ms. Doe is a beneficiary of an employee welfare plan -- health insurance -- and is seeking to recover benefits due under that plan, enforce her rights under the plan, clarify her right to future benefits, redress violations of ERISA.

3. Pursuant to 29 U.S.C. § 1132(f), this Court has jurisdiction without respect to the amount in controversy or citizenship of the parties to grant the relief Ms. Doe seeks, and jurisdiction is also invoked pursuant to 28 U.S.C. § 1331.

4. Ms. Doe has exhausted the administrative remedies and appeals provided by UHC and the health insurance plan.

5. Attorneys' fees and costs may be awarded pursuant to 29 U.S.C. § 1132(g).

6. This action properly lies in the Southern District of Ohio, Eastern Division, pursuant to 28 U.S.C. § 1391(b); 29 U.S.C. § 1132(e)(2); and under S.D. Civ.R. 82.1, because UHC provided insurance coverage to an employer headquartered in Franklin County, Ohio, and the events giving rise to this action occurred when Ms. Doe sought reimbursement for drugs she was prescribed, purchased, and used in Franklin County.

III. Parties

7. Plaintiff Jane Doe, who have filed a motion for leave to proceed by pseudonym, is age 18, 5'5" and, at the time of her diagnosis, treatment, and application for benefits weighed around 300 pounds; was, at all times material to this Complaint, a beneficiary of a UHC health insurance plan in which her mother was a participant; timely sought benefits under that plan, was denied those benefits, and timely and completely exhausted her internal appeal from that denial;

and continues to take and pay for, without reimbursement, the prescription that UHC has deemed not covered.

8. Defendant UHC is, by United States market share, the largest health insurance company based in the United States, providing benefits coverage to more than 250,000 employers; including Plan #: 1L9930 for the employer of Ms. Doe's mother, who was at all time material to this action, a participant covered by UHC insurance; and has discretion under that policy to determine the eligibility of participants and beneficiaries for reimbursement of their expenses on prescribed drugs.

IV. Facts

9. By letter dated August 8, 2022, UHC notified Ms. Doe that "an independent review company, CoreAdvisory" had upheld its denial of her benefits application.

10. CoreAdvisory reached that decision on or about June 15, 2022, based on its reviewer's characterization of the issue as "whether Ozempic is medical necessary."

11. The entire answer of the reviewer was: "Upon independent review the reviewer finds that the previous determination/adverse determinations should be: Upheld (Agree)."

12. UHC provided that review based upon the Ohio Department of Insurance process for appealing adverse determinations on the grounds of "experimental/investigational" prescription drugs.

13. In denying Ms. Doe benefits UHC had given a single specific ground: Ozempic is approved only for treating those who already have type 2 diabetes mellitus.

14. Neither CoreAdvisory nor its independent reviewer addressed Ms. Doe's appeal from the denial that Ozempic had actually been approved for those, like her, who were prediabetic with one or more aggravating conditions.

15. Ms. Doe has been diagnosed as morbidly obese, insulin resistant, and prediabetic.

16. Her treating physician, Jennifer S. Dyer, MD, MPH, FAAP, Central Ohio Pediatric Endocrinology and Diabetes Services, prescribed Ozempic for her, determining its use a medical necessity for treating the symptoms of prediabetes/type 2 diabetes related to her obesity.

17. For years, Ms. Doe has fought obesity, and UHC has paid toward prescriptions for, among other drugs, Metformin.

18. Dr. Dyer determined, based on in-person examinations of Ms. Doe, knowledge of her medical history, and observance of her lack of progress on Metformin, that prescribing Metformin was inefficacious.

19. Metformin is a widely prescribed inexpensive drug for chronic weight management in adults with obesity, while Ozempic is a very expensive drug that the FDA approved on June 4, 2021, for chronic weight management in adults with obesity or overweight with at least one weight-related condition.

20. Ms. Doe is an adult with obesity and at least one weight-related condition, including abdominal and menstrual pain, cramping, difficulty breathing, a recurring nodule between her breasts, and psychological and emotional problems, and, in addition to Ozempic and Metformin, has taken during the period from July 31, 2021, to January 31, 2022, potent medications, including Amitriptyline, an antidepressant; Cephalexin, an antibiotic; Dicyclomine, an antispasmodic for cramps; Escitalopram, another antidepressant also prescribed for anxiety and premenstrual symptoms; Ondansetron, an antidote to body chemicals that trigger nausea and vomiting; Pen Needles for insulin injection; and Trazodone, another antidepressant.

21. UHC reimbursed Ms. Doe or her parents for each of those prescriptions other than Ozempic.

22. Although UHC stated its reason for denying coverage of Ozempic was that it may only be prescribed for type 2 diabetes mellitus, UHC showed no such concern for Ms. Doe taking Metformin, even though it too is mainly used to treat type 2 diabetes mellitus.

23. Ms. Doe first started taking Ozempic in January when her doctors procured free samples for her.

24. While the initial low dosages had little impact, as higher dosages were given, Ms. Doe was able to lose some weight and seemingly begin to slow or prevent the onslaught of type 2 diabetes.

25. For years, Ms. Doe's insulin resistant condition had thwarted efforts to lose weight because she remained hungry even after she had eaten and turned to snacks and more food.

26. Ms. Doe's concern with her weight heightened when she was diagnosed initially as prediabetic and later as insulin resistant; she has sought medical treatment for those conditions, rather than simply wanting help with dieting or her appearance.

27. Ms. Doe wants to avoid developing type 2 diabetes mellitus and fears that, unless effective medication is available now, she will not only develop that disease but also find treating it far more difficult the heavier she gets and the more challenging her weight-related conditions become.

28. Ozempic had enabled Ms. Doe to lose 50 pounds, develop a healthy eating regimen, and use intermittent fasting to help her metabolism and is anticipated by both her and her doctor to stave off diabetes.

29. For at least five years, none of the other medications and interventions Ms. Doe tried approached the effectiveness of Ozempic.

30. Early in her teens, Ms. Doe spent more than six months going to appointments with nutritionists at Nationwide Children's Hospital, learning about health diets.

31. Ms. Doe's efforts to implement that learning did not stem her emerging obesity.

32. Ms. Doe soon developed a dread of helplessness and feeling bad about herself, bordering on depression.

33. Ms. Doe did not then know about her insulin resistant condition and blamed personal weakness, rather than that condition, on her emerging obesity.

34. Ms. Doe developed a quick temper and angrily melted down whenever family members intervened to limit her eating.

. Ms. Doe's self-image deteriorated with the guilt of what became a vicious cycle, and she was using food not only when hungry but also in rebellion.

35. At age 15 Ms. Doe reported to a doctor that she had struggled with weight her whole life, with every medical appointment involving increased concern about emerging obesity.

36. Over the years Ms. Doe's frustration of being unable to find any combination of medicines and programs to deal with the obesity mounted.

37. Ms. Doe started being treated by a psychiatrist for anger issues revolving around food, but she was embarrassed that she needed that treatment, and the sadness and anger remained.

38. Ms. Doe's relationships with her immediate family, friends, and, later, a boyfriend all suffered from a constant focus on her being overweight; when, what, how much, and why she ate; and the potential for serious health repercussions.

39. At the end of middle school and start of high school, Ms. Doe added to her regular physical activity, playing sports five or so days a week and informal sports several days, walking the dogs, and riding her bicycle on lengthy trips.

40. Nothing worked, and even Ms. Doe's participation on the school team suffered as her obesity prevented exercising as much as the other team members.

41. Ms. Doe does not remember the precise point when she realized just what prediabetic really meant and how type 2 diabetes mellitus could affect her.

42. Ms. Doe knows, though, that the harm type 2 diabetes mellitus could inflict, depending on how well medication and other efforts work, might be devastating.

43. Once Ms. Doe understood that she was insulin resistant and how that condition contributed to her morbid obesity, she became more committed than ever to a cure.

44. Ozempic gave Ms. Doe the first hope that her future would be brighter than her past.

45. Ms. Doe has been admitted to university, wants to start her academic career without the fear of contracting type 2 diabetes mellitus, and is convinced that Ozempic is the only way for her to do so.

46. Ozempic, also referred to when prescribed solely for weight loss as Wegovy, is a semaglutide, which mimics the production of hormones, including insulin, by the pancreas; is administered by weekly injection from prefilled, disposable pens; is not available as a generic; and a monthly dosage retails, with coupons, around \$900.00.

47. Metformin, also known under the brand names of *Glucophage*, *Fortamet*, *Glumetza*, and *Riomet*, is a member of a class of biguanides, which inhibit the production of glucose in the liver; is taken on a daily basis orally in pill form; is available as a generic; and a monthly dosage, such as 100 500 mg pills, costs \$8.00.

48. UHC decides whether to reimburse participants and beneficiaries and pays reimbursement when it decides the participant or beneficiary is eligible under one of its plans.

49. UHC has a structural conflict of interest because it charges employers a premium for a health insurance policy that does not fluctuate depending on the expense of medications for which participants and beneficiaries seek reimbursement; consequently, UHC tilts against reimbursing for an expensive drug, like Ozempic, while favoring reimbursement of an inexpensive drug, like Metformin, even though circumstances other than cost are similar in all material respects.

50. When UHC denied reimbursement to Ms. Doe for Ozempic, it invoked the health insurance policy exclusion for experimental, investigational, or unproven drugs: “Experimental or Investigational and Unproven Services and all services related to Experimental or Investigational and Unproven Services are excluded. The fact that an Experimental or Investigational or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental or Investigational or Unproven in the treatment of that particular condition.”

On January 24, 2022, UHC wrote in its Pharmacy Clinical Appeals Review Form, Case No.: PA-98038833, “This medicine is covered only if: You have a diagnosis of type 2 diabetes mellitus.”

On February 5, 2022, the UHC Medical Director recognized that Ms. Doe “would take this drug for obesity with insulin resistance/pre-diabetes.”

51. UHC typically relies on FDA approval in determining whether a prescription drug is no longer experimental, investigational, or unproven.

52. At no time has UHC explained or described why Ozempic is experimental, investigational, or unproven for the treatment of Ms. Doe’s conditions.

53. In a remarkable turn of events, by letter dated October 17, 2022, the mail-order pharmacy OptumRx (trademarked) wrote to Ms. Doe and said: “OptumRx on behalf of UnitedHealthcare, is responsible for reviewing pharmacy services provided to UnitedHealthcare members. OptumRx received request on 10/17/2022 from your prescriber of coverage of Ozempic Inj 2/1.5ml. Your request for Ozempic Inj 2/1.5ml has been approved.”

54. Despite UHC’s approval of coverage for Ozempic, and after requests from Ms. Doe’s counsel to do so, UHC has failed and refused to reimburse Ms. Doe for several thousand dollars she had to pay out of pocket for the medication before the recent approval.

V. Claim for Relief: ERISA Violations

55. Paragraphs 1-54 are incorporated herein as if fully set forth.

56. By abusing its discretion in denying reimbursement to Ms. Doe for a prescription drug that is not excludable as experimental, investigational, or unproven and then depriving her of a full and fair review by pulling a bait-and-switch in asking an independent reviewer whether the drug was medically necessary on an administrative record where the detailed and documented opinion of the treating physician was not addressed, let alone convincingly distinguished, and the inconsistent treatment of a similar, far less expensive drug unreconciled, UHC has violated ERISA.

VI. Prayer for Relief

WHEREFORE, Plaintiff prays judgment against Defendant,

- a. declaring that Defendant has violated ERISA;
- b. ordering such equitable, injunctive, and monetary relief as will make her whole for Defendant’s refusal to reimburse her; prejudgment and postjudgment interest, costs, attorneys’ fees, and
- c. granting such other relief as the Court may deem appropriate.

Respectfully submitted,

By: /s/ John S. Marshall

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